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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

RALICA ZAMFIROVA, RACHAEL	:	
MAHER, JASMIN AMARO,	:	
MARINA GOMEZ, ANGELE	:	Civil Action No.: 20-00152 (JMV)(SCM)
NELSON, REBECCA TORRES,	:	
CAROLYN GILL, MARY JO	:	
BARNES, TERESA FAUGHNAN,	:	
JENNIFER MALTESE, LISA	:	<b>PLAINTIFFS' CONSOLIDATED</b>
BRADY, and KIMBERLY	:	<b>AMENDED CLASS ACTION</b>
MEFFERT, individually and on behalf	:	<b>COMPLAINT AND JURY</b>
of others similarly situated,	:	<b>DEMAND</b>
	:	
<i>Plaintiffs,</i>	:	
	:	
v.	:	
	:	
AMAG PHARMACEUTICALS, INC.,	:	
	:	
<i>Defendant.</i>	:	
	:	

Plaintiffs Ralica Zamfirova, Rachael Maher, Jasmin Amaro, Marina Gomez, Angele Nelson, Rebecca Torres, Carolyn Gill, Mary Jo Barnes, Teresa Faughnan, Jennifer Maltese, Lisa Brady, and Kimberly Meffert bring this case on behalf of

themselves and all others similarly situated against defendant AMAG Pharmaceuticals, Inc., and in support thereof state:

#### **NATURE OF THE CASE**

1. This case arises from Defendant's marketing and sale of the prescription drug Makena, a hydroxyprogesterone caproate. Defendant purchased the exclusive right to manufacture Makena, raised the price when it sold Makena to outrageous levels, and continued marketing and selling Makena under the false guise that it would help prevent premature births even when it knew that to be untrue. Independent third-party studies have shown that Makena is ineffective for that purpose.

#### **PARTIES AND BACKGROUND**

2. Plaintiff Ralica Zamfirova resides in Northvale, Bergen County, New Jersey. During the class period, Ms. Zamfirova was prescribed, injected with, and purchased Makena. Ms. Zamfirova paid out of pocket for Makena.

3. Plaintiff Rachael Maher resides in Neptune, Monmouth County, New Jersey. During the class period, Ms. Maher was prescribed, injected with, and purchased Makena. Ms. Maher paid insurance co-pays for her Makena treatments.

4. Plaintiff Jasmin Amaro is a Los Angeles, California resident. During the class period, Ms. Amaro was prescribed, injected with, and purchased Makena

during three pregnancies and went into preterm labor multiple times during each of those pregnancies, while on Makena. Ms. Amaro paid out of pocket for Makena.

5. Marina Gomez resides in Davis, California. During the class period, Ms. Gomez was prescribed, injected with, and purchased Makena. Ms. Gomez paid out of pocket for Makena.

6. Plaintiff Angele Nelson resides in Yuba City, California. During the class period, Ms. Nelson was prescribed, injected with, and purchased Makena. Ms. Nelson paid out of pocket for Makena.

7. Rebecca Torres resides in Riverside, California. During the class period, Ms. Torres was prescribed injected with, and purchased Makena. Ms. Torres paid out of pocket for Makena.

8. Plaintiff Carolyn Gill resides in Leawood, Kansas. During the class period, Ms. Gill was prescribed, injected with, and purchased Makena. While taking Makena, Ms. Gill's child was born at 37 weeks. Ms. Gill paid out of pocket for Makena.

9. Plaintiff Mary Jo Barnes resides in Miller, Missouri. During the class period, Ms. Barnes was prescribed, injected with, and purchased Makena. Ms. Barnes began taking Makena during her 16<sup>th</sup> week of pregnancy and delivered her baby preterm at 24 weeks. The baby died shortly thereafter. Ms. Barnes continues to

pay for this previous preterm care, including her Makena shots, via a payment plan after her medical provider referred her to collections.

10. Teresa Faughnan resides in Apalachin, New York. During the class period, Ms. Faughnan was prescribed, injected with, and purchased Makena. Ms. Faughnan's child was born preterm at 36 weeks. Ms. Faughnan paid out of pocket for Makena.

11. Jennifer Maltese resides in East Northport, New York. During the class period, Ms. Maltese, was prescribed, injected with, and purchased Makena. While on Makena, Ms. Maltese had four children born preterm (two at 35 weeks, one at 34 weeks, and one at 32 weeks). Ms. Maltese paid out of pocket for Makena.

12. Lisa Brady resides in Pewaukee, Wisconsin. During the class period, Ms. Brady was prescribed, injected with, and purchased Makena. Ms. Brady paid out of pocket for Makena.

13. Kimberly Meffert resides in Whitewater, Wisconsin. During the class period, Ms. Meffert was prescribed, injected with, and purchased Makena. Ms. Meffert paid out of pocket for Makena.

14. Defendant AMAG Pharmaceuticals, Inc. ("AMAG") is a Delaware corporation headquartered in Waltham, Massachusetts. AMAG is a publicly traded company. (Nasdaq: AMAG). AMAG currently holds the exclusive rights to Makena.

## **JURISDICTION AND VENUE**

15. Venue is proper in this District under 28 U.S.C. § 1391(b) because at all times relevant to the Complaint: (a) AMAG transacted business, was found, or acted through subsidiaries or agents present in this District; and (b) a substantial part of the events giving rise to Plaintiffs' claims occurred in this District. Alternatively, venue lies under 28 U.S.C. § 1391(c) because AMAG is subject to the Court's personal jurisdiction.

16. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d) because the case is a class action, the class members are diverse from AMAG, and the amount in controversy exceeds \$5,000,000.

17. This Court has personal jurisdiction over AMAG because AMAG transacted business in this District.

## **FACTUAL ALLEGATIONS**

### **I. History of Hydroxyprogesterone Caproate and Makena**

18. The hormonal medication hydroxyprogesterone caproate has been in the U.S. marketplace since 1956. Over time, the pharmaceutical companies have not added anything new to this drug—failing to make the drug a viable product for mothers at risk of premature births and failing to mitigate the potential adverse consequences of taking hydroxyprogesterone caproate. The only real addition by the manufacturers have been enormous price increases.

19. Shering AG developed hydroxyprogesterone caproate in 1953 and reported its medical effects in 1954.<sup>1</sup> The drug was first marketed in Japan in 1954-55 before it was introduced in the United States in 1956 by Squibb, having acquired the license to the patent, under the brand name Delalutin to manage abnormal bleeding in patients with uterine cancer.<sup>2</sup>

20. In the 1960s, Delalutin began to be used to treat pregnant women who had tumorous ovaries removed.<sup>3</sup>

21. In the 1990s, Delalutin (and thus hydroxyprogesterone caproate) had become a leading drug to treat an imminent premature birth threat during pregnancy after studies focused on its potential to reduce preterm births.<sup>4</sup>

22. Bristol Meyer Squibb voluntarily withdrew the drug from the market in

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<sup>1</sup> Ralph I. Dorfman, *Methods in Hormone Research*, Academic Press (1966).

<sup>2</sup> Lippincott, *New and Nonofficial Drugs*, Council on Drugs (1964); *see also* Tom Morrow, MD, *Resurrection of Preterm Labor Drug Evokes Questions of Fairness*, Biotechnol. Healthc. 2011, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3138388/>.

<sup>3</sup> Macintyre, *Ovarian surgery with loss of corpus luteum in early pregnancy. Report of two cases brought to term with progestin (Delalutin) therapy*, Can. Med. Assoc. J. (1961), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1848126/pdf/canmedaj00899-0006.pdf>.

<sup>4</sup> Keirse, *Progestogen administration in pregnancy may prevent preterm delivery*, Obstet. Gynaecol. (Feb. 1990); *see also* Morrow, *Resurrection of Preterm Labor Drug Evokes Questions of Fairness*.

1999.<sup>5</sup>

23. Hologic, Inc. is a Delaware corporation, headquartered in Marlborough, Massachusetts. Hologic (NASDAQ: HOLX) is a multinational, publicly-traded corporation. Hologic developed and originally held the exclusive rights to Makena. Hologic sold the exclusive rights to Makena to KV Pharmaceuticals shortly after Hologic obtained FDA approval in early 2011.<sup>6</sup>

24. KV Pharmaceutical was forced to file for chapter 11 bankruptcy and re-emerged under the name Lumara Health (“Lumara”) in 2013.<sup>7</sup>

25. Thereafter, Lumara continued to manufacture, market, and sell Makena.

26. Interest in hydroxyprogesterone caproate resurged after a 2013 study

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<sup>5</sup> *Determination that Delalutin Injection, 125 mg/ mL and 25 mg/ mL, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness*, FDA (June 25, 2010), <https://www.federalregister.gov/documents/2010/06/25/2010-15416/determination-that-delalutin-hydroxyprogesterone-caproate-injection-125-milligramsmilliliter-and-250>.

<sup>6</sup> FDA, Accelerated Approval Letter for New Drug Application 21945 (Feb. 3, 2011), [https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2011/021945s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2011/021945s000ltr.pdf).

<sup>7</sup> Angela Mueller, *Former KV Pharmaceutical to be Acquired*, St. Louis Business Journal (2014), <https://www.bizjournals.com/stlouis/blog/health-care/2014/09/former-kv-pharmaceutical-to-be-acquired.html>.

appeared to find that it might reduce the risk of preterm births in at-risk mothers.<sup>8</sup>

27. In 2014, AMAG bought Lumara for \$675 million and an additional \$350 million contingent on sales milestones.<sup>9</sup> The flagship product in the acquisition was Makena.

## **II. Makena Receives FDA Fast-Track Approval**

28. FDA fast-track approval for prescription drugs was created to expedite the development and review of drugs that treat serious conditions and fill an unmet medical need.<sup>10</sup>

29. The “New Drug Application” or NDA seeking accelerated approval for Makena was approved by the FDA on February 3, 2011.<sup>11</sup>

30. The data used to support Makena’s fast-track application and subsequent

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<sup>8</sup> Meis PJ, *et al*, *Prevention of Recurrent Preterm Delivery By 17 Alpha-Hydroxyprogesterone Caproate*, New England Journal of Medicine (June 2013), 348(24):2379-2385, <https://www.nejm.org/doi/full/10.1056/NEJMoa035140>.

<sup>9</sup> Grogan, *AMAG \$1 Billion Deal to Buy Preterm Birth Drug Makena*, [http://www.pharmatimes.com/news/amag\\_\\$1\\_billion\\_deal\\_to\\_buy\\_preterm\\_birth\\_drug\\_makena\\_1002541](http://www.pharmatimes.com/news/amag_$1_billion_deal_to_buy_preterm_birth_drug_makena_1002541).

<sup>10</sup> Fast Track, FDA (current as of Jan. 4, 2018), <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>.

<sup>11</sup> FDA, Accelerated Approval Letter for New Drug Application 21945 (Feb. 3, 2011), [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2011/021945s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021945s000ltr.pdf)



approval, though, was insufficient to assess Makena's efficacy.<sup>12</sup>

31. The FDA relied heavily on a single clinical trial published in 2003 by the National Institute of Child Health and Human Development ("NICHD").<sup>13</sup> The FDA's Statistical Review and Evaluation, however, found that reliance solely on the 2003 NICHD study was insufficient to establish the efficacy of the drug in preventing preterm births.<sup>14</sup>

32. Analysis of the NICHD trial found that: 1) the study failed to identify the optimal time to start taking Makena; 2) one study center accounted for nearly half of the subjects, calling into question the effectiveness of the study's randomizations; and 3) women treated with Makena experienced fetal and neonatal deaths earlier than women who were taking the placebo.<sup>15</sup>

33. The statistical review concluded that Makena's medical benefits in reducing

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<sup>12</sup> Jim Doyle, *FDA's Fast-Track Approval of Makena Could Backfire on KV*, St. Louis Post-Dispatch (Mar. 13, 2011), [https://www.stltoday.com/business/local/fda-s-fast-track-approval-of-makena-could-backfire-on/article\\_e4472916-0646-539d-b04a-520756765418.html](https://www.stltoday.com/business/local/fda-s-fast-track-approval-of-makena-could-backfire-on/article_e4472916-0646-539d-b04a-520756765418.html).

<sup>13</sup> Meis PJ, *et al.*, *Prevention of Recurrent Preterm Delivery By 17 Alpha-Hydroxyprogesterone Caproate*, N Eng J Med. (June 2013), 348(24):2379-2385, <https://www.nejm.org/doi/full/10.1056/NEJMoa035140>.

<sup>14</sup> Statistical Review and Evaluation: Clinical Studies (21-945 Makena), FDA (July 13, 2010), [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2011/021945Orig1s000StatR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/021945Orig1s000StatR.pdf).

<sup>15</sup> *Id.* at 6.

preterm births were “**not convincing** when considering that only one study was submitted to support the claim of effectiveness” for hydroxyprogesterone caproate.<sup>16</sup>

34. Despite the FDA’s own statisticians’ misgivings about the effectiveness of Makena, the FDA approved it on a fast-track basis, allowing the drug to hit the U.S. market shortly thereafter.<sup>17</sup>

### **III. Makena Is Exorbitantly Priced and Doesn’t Work**

35. In 2008, Hologic, who owned the rights to Makena, and KV Pharmaceutical entered into an agreement giving KV Pharmaceutical worldwide rights to manufacture, market, and sell Makena.<sup>18</sup>

36. The Orphan Drug Act, 21 U.S.C. § 360aa, was intended to attract pharmaceutical companies to develop drugs designed to treat rare but serious conditions like ALS, Tourette syndrome and muscular dystrophy.<sup>19</sup> Under the

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<sup>16</sup> *Id.* at 39.

<sup>17</sup> FDA, Accelerated Approval Letter for New Drug Application 21945 (Feb. 3, 2011), [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2011/021945s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021945s000ltr.pdf).

<sup>18</sup> Lisa Brown, *KV Pharmaceutical, hologic Settle Makena Dispute*, St. Louis Post-Dispatch (Dec. 13, 2012), [https://www.stltoday.com/business/local/kv-pharmaceutical-hologic-settle-makena-dispute/article\\_79fd8d56-bd16-51fe-9225-a6ac33d8ba8a.html](https://www.stltoday.com/business/local/kv-pharmaceutical-hologic-settle-makena-dispute/article_79fd8d56-bd16-51fe-9225-a6ac33d8ba8a.html).

<sup>19</sup> Richard Knox, *Premeire Prevention Drug Costs 53 Times More Than Generic, But Researches Find it’s No Better*, WBUR 90.9 (Oct. 3, 2017),

Orphan Drug Act, an “orphan drug” is a drug used to treat a disease or condition that affects fewer than 200,000 people in the United States or lacks commercial viability.

37. Section 360cc of the Orphan Drug Act grants drug companies exclusive marketing rights for a drug that treats a rare disease or condition for up to seven years. Makena was designated as an “orphan drug” under the Act in 2007.<sup>20</sup>

38. Makena hit the market with a breathtaking sticker price: \$1,500 per injection, up from the generic \$10-\$20 price. Women who were taking the generic drug were understandably shocked: “I’m ready to have a heart attack,” Janice Watkins, who had been taking the generic drug known as 17P, said in 2011 after she learned of the price increase from her doctor’s office.<sup>21</sup> “I’m nervous now because I have to go home and call my insurance company to see if they’ll cover me.”<sup>22</sup>

39. Due to public outrage over KV Pharmaceutical’s expected price hike, the FDA allowed compounding pharmacies to make the generic drug 17P in their

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<https://www.wbur.org/commonhealth/2017/10/03/preterm-birth-prevention-drug-costs>.

<sup>20</sup> *Id.*

<sup>21</sup> <https://www.post-gazette.com/news/health/2011/03/11/Pregnancy-drug-s-sharp-price-hike-called-greed/stories/201103110343>.

<sup>22</sup> David Whelan, Forbes, “Is KV Pharmaceutical A Flat-Out Evil Company?” available at <https://www.forbes.com/sites/davidwhelan/2011/03/11/is-kv-pharmaceutical-a-flat-out-evil-company/#11da813831b5>.

pharmacies in order to allow a more affordable option for mothers.<sup>23</sup>

40. Eventually, in large part due to market pressure from compounded 17P, KV Pharmaceutical reduced the price to \$690 per Makena injection.<sup>24</sup>

41. Since acquiring Lumara, AMAG has continued price-gouging its customers.

42. As one woman reported: “Insanely expensive - did not find this out until half way through my amount of injections that they were charging my insurance \$1500 per shot! Insurance ‘covered’ half leaving me with \$750ish a shot. No one told me they would be this expensive. Hopefully I can save someone the surprise.”<sup>25</sup>

43. A 2017 Harvard study, which analyzed a database of insurance claims for Makena, noted Makena cost 100 times more than the original compounded 17P. The Study found that the average cost per pregnancy of Makena was \$10,917 compared to \$206 for the compounded version.<sup>26</sup>

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<sup>23</sup> Alexander Gaffney, *FDA Maintains Compounding Exemption for KV Pharmaceutical’s Makena*, Regulatory Focus (June 18, 2012), <https://www.raps.org/regulatory-focus/news-articles/2012/6/fda-maintains-compounding-exemption-for-kv-pharmaceuticals-makena>.

<sup>24</sup> *Id*; see also Senator Sherrod Brown Statement on Makena Repricing.

<sup>25</sup> Comment posted Sept. 18, 2019, <https://www.drugs.com/comments/hydroxyprogesterone/makena.html> (accessed Oct. 30, 2019).

<sup>26</sup> See “Utilization, Cost, and Outcome of Branded vs Compounded 17-Alpha Hydroxyprogesterone Caproate in Prevention of Preterm Birth” available at <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2655241>.

44. The same study found no statistically significant difference in the rate of preterm births between the women who received Makena and the women receiving compounded 17P.<sup>27</sup>

45. The same study further concluded that despite FDA concerns regarding compounded drugs, the frequency of infections during treatment regimens was equally low among the women receiving compounded 17P and the women receiving Makena.<sup>28</sup>

46. This study concluded that the “analysis raises concerns about the value of hydroxyprogesterone caproate.”<sup>29</sup>

47. Each of the named Plaintiffs paid at least hundreds of dollars for each shot of Makena.

#### **IV. AMAG’s and its Predecessor’s Attacks on Affordable Generics**

48. AMAG and its predecessors, who – again, did not discover a novel drug or invent 17P and instead relied on an NIH-funded study to receive orphan drug status have aggressively attacked generic, compounded versions of 17P. AMAG and its predecessors made these attacks to protect their scandalous pricing regime over an ineffective drug.

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<sup>27</sup> *See id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

49. Doctors and pharmacy directors often fear the repercussions of prescribing a compounded hydroxyprogesterone caproate over an FDA-approved product because any unforeseen side effect due to the compounded drug could result in liability for the medical professional or pharmacist.<sup>30</sup>

50. AMAG and its predecessors have aggressively sought to capitalize on such concerns to force the FDA to remove compounded versions of 17P.

51. While AMAG and its predecessors have couched these attacks as concerns for safety and efficacy, these unfounded attacks are simply an excuse for charging outrageous prices and reaping the profits.

52. In 2012, after lawmakers and insurers complained that KV was engaged in price gouging, the FDA refused to stop compounding pharmacies from making 17P. Despite evidence to the contrary, KV argued that compounded versions of 17P weren't as effective or as safe as Makena and should therefore be taken off the market by the FDA. In response to KV's pressure, the FDA tested 16 samples of compounded 17P. While the FDA noted in its conclusions that approved products may generally provide assurance of safety and efficacy, the FDA concluded that the 16 tested samples of generic 17P posed no major safety risks.<sup>31</sup>

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<sup>30</sup> *Id.*

<sup>31</sup> "K-V sues FDA over Makena in Fight for Survival." Anna Yukhanano, Reuters, July 5, 2012, available at <https://www.reuters.com/article/us-fda-makena/k-v-sues-fda-over-makena-in-fight-for-survival-idUSBRE86502T20120706>.

53. Around the same time, the FDA also noted that KV was misrepresenting the FDA's position on compounded 17P. The FDA noted in a press release that KV was attempting to stop compounding pharmacies by sending the compounding companies misleading letters and threatening to sue for continuing to sell compounded 17P at a fraction of the cost of Makena.<sup>32</sup>

54. In these letters KV falsely claimed that the FDA would not exercise enforcement discretion regarding compounding of generic 17P. The FDA responded that, "FDA understands that the manufacturer of Makena, KV Pharmaceuticals has sent letters to pharmacists indicating that FDA will no longer exercise enforcement discretion with regard to compounded versions of Makena. This is not correct."<sup>33</sup>

55. In 2012, after the FDA refused to bow to KV's pressure campaign and initiate enforcement against compounding pharmacies, KV sued the FDA to stop compounding of generic 17P.

56. KV's suit against the FDA was dismissed by the district court in short order, roughly two months after KV filed suit.<sup>34</sup>

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<sup>32</sup> *Id.*

<sup>33</sup> *See KV Pharmaceutical Company, et al., v. United States Food and Drug Administration, et al.* Doc. 23 at 4-5, Case No. 12-cv-01105 (D.D.C. Sept. 6, 2012).

<sup>34</sup> *See id.* The case was eventually vacated and remanded for further consideration by the D.C. Circuit Court. KV dismissed its case against the FDA with prejudice on July 3, 2014. *See id.* (Docs. 27, 34).

57. AMAG has echoed KV's attempts to cast compounding pharmacies as unsafe and lower quality. In a briefing document submitted to the FDA to persuade the FDA to keep Makena on the market, AMAG raised the specter of impure, contaminated compounded drugs as a reason to allow AMAG to continue to market Makena.<sup>35</sup>

## **V. The PROLONG Study Definitively Shows that Makena Does Not Work**

58. The fast-track approval of Makena was conditioned on a follow-up, long-term clinical trial to confirm the efficacy of hydroxyprogesterone caproate in preventing preterm births.<sup>36</sup>

59. On March 8, 2019, after 8 years of Makena sales at unconscionable prices, AMAG revealed the results of the FDA-mandated follow-up trial, known as the PROLONG (Progestin's Role in Optimizing Neonatal Gestation) study ("PROLONG Study").

60. The PROLONG Study included approximately 1,700 pregnant women and examined the efficacy of Makena versus a placebo in preventing preterm births in women who had a history of spontaneous preterm births. The study was a

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<sup>35</sup> Makena NDA 021945/S-023, Advisory Comm. Briefing Document (Oct. 29, 2019), pp. 34-35.

<sup>36</sup> FDA, Accelerated Approval Letter for New Drug Application 21945 (Feb. 3, 2011), [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2011/021945s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021945s000ltr.pdf)



randomized, double-blinded, placebo-controlled clinical trial.<sup>37</sup>

61. According to AMAG, 11% of the women in the study who took Makena delivered their babies at 35 weeks or earlier; whereas 11.5% of women who took the placebo delivered their babies at 35 weeks or earlier. There were also no statistically significant differences concerning miscarriages and stillbirths (adverse events) between Makena and the placebo treatment.<sup>38</sup>

62. The PROLONG Study showed that Makena was no more effective than a placebo. AMAG admitted that the PROLONG Study's results showed no "statistically significant difference between the treatment [Makena] and placebo arms for the co-primary endpoints." The results also showed there was no significant difference between subjects using Makena and subjects using placebos on the rate of neonatal mortality or morbidity.<sup>39</sup> Put differently: the PROLONG Study was further evidence that Makena doesn't work.

63. On October 29, 2019, and based on the results of the PROLONG Study, the FDA Bone, Reproductive and Urologic Drugs Advisory Committee recommended

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<sup>37</sup> AMAG Pharmaceuticals Announces Topline Results from the Prolong Trial Evaluating Makena, AMAG Pharmaceuticals (Mar. 8, 2019), <https://www.amagpharma.com/news/amag-pharmaceuticals-announces-topline-results-from-the-prolong-trial-evaluating-makena-hydroxyprogesterone-caproate-injection>.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

that Makena be withdrawn from the market.<sup>40</sup>

64. On information and belief, both because of the original problems with the Meiss study, and because the incoming data for the PROLONG trial were showing Makena was ineffective, AMAG knew far earlier than finalization of the PROLONG Study that Makena was ineffective.

65. After the PROLONG trial, the health insurance industry has signaled it will no longer pay claims for Makena treatment due to Makena's inefficacy. A spokesperson for America's Health Insurance Plans (AHIP), a national association representing the health insurance industry, recently confirmed that the PROLONG study definitively shows that Makena doesn't work. According to that spokesperson, Cathryn Donaldson, "Now it is clear it is not effective."<sup>41</sup>

66. On the heels of the PROLONG study and its finding of inefficacy, AMAG has responded with substantial restructuring of its leadership and its business.

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<sup>40</sup> Sumanthi Reddy, *FDA Committee Recommends Withdrawing Treatment to Prevent Preterm Births From Market*, The Wall Street Journal (Oct. 29, 2019), <https://www.wsj.com/articles/fda-committee-recommends-withdrawing-treatment-to-prevent-preterm-births-from-market-11572387799>; see also Ned Pagliarulo, *FDA Panel Backs Withdrawal of AMAG Drug to Prevent Preterm Birth*, BiopharmaDive (Oct. 30, 2019), <https://www.biopharmadive.com/news/amag-makena-fda-advisory-panel-vote-withdrawal-preterm-birth/566159/>.

<sup>41</sup> Emmarie Huettelman, NPR. "Drug to Prevent Premature Birth Divides Doctors, Insurers, and FDA Experts." <https://www.npr.org/sections/health-shots/2020/01/24/798731110/drug-to-prevent-premature-birth-divides-doctors-insurers-and-fda-experts>.

67. AMAG announced in January that its President and CEO William Heiden is stepping down, and the Board of Directors is currently searching for Mr. Heiden's replacement.<sup>42</sup>

68. AMAG is also undergoing significant changes to its medical development organization. On March 31, 2020, Dr. Julie Krop, Executive Vice President and Chief Medical Officer left AMAG.<sup>43</sup>

69. After the PROLONG study AMAG has also claimed that removal of Makena from the market may exacerbate inequitable outcomes in healthcare. Citing purported demographic differences between the Meiss and PROLONG study, and in response to criticisms of the Meiss study, AMAG opposed removing Makena from the market, stating: "Withdrawing the only FDA-approved intervention could have the unintended consequence of further exacerbating existing health disparities associated with preterm birth in the most vulnerable patient populations."<sup>44</sup>

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<sup>42</sup> AMAG Newsroom, "AMAG Pharmaceuticals Announces Leadership Transition, Results of Strategic Review to Unlock Shareholder Value and Financial Update" <https://www.amagpharma.com/news/amag-pharmaceuticals-announces-leadership-transition-results-of-strategic-review-to-unlock-shareholder-value-and-financial-update/>.

<sup>43</sup> AMAG Newsroom, "AMAG Pharmaceuticals Announces Changes to Medical Development Organization," Mar. 4, 2020, available at <https://www.amagpharma.com/news/amag-pharmaceuticals-announces-changes-to-medical-development-organization/> last accessed Mar. 19, 2020.

<sup>44</sup> <https://www.amagpharma.com/news/amag-files-response-to-citizen-petition/>.

70. Currently, the FDA has not yet removed Makena from the U.S. market.

71. AMAG has made hundreds of millions (if not billions) of dollars in sales of Makena during the relevant time frame. In 2018, AMAG reported revenue for operations of approximately \$474 million, with Makena contributing the lion's share of AMAG's annual revenue at \$323 million.<sup>45</sup>

## **VI. Makena Is Marketed to Women as a Drug to Prevent Preterm Births**

72. AMAG's website markets Makena to pregnant moms, saying: "Makena helps you get closer to term"; "Makena...is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past"; and "Makena gives moms an extra layer of support."<sup>46</sup>

73. AMAG's marketing uses testimonials of how effective Makena was for other moms, including one mother stating that "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy" and another mother saying, "looking back, Makena gave

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<sup>45</sup> AMAG 2018 Financial Results (Feb. 7, 2019), <https://www.amagpharma.com/news/amag-reports-fourth-quarter-and-full-year-2018-financial-results-and-provides-company-update/>.

<sup>46</sup> *Reducing Risk with Makena Auto-Injector*, Makena (hydroxyprogesterone caproate injection), <https://makena.com/reducing-preterm-birth-risk-with-makena/>.

me hope that I had a better chance of delivering Olivia full term.”<sup>47</sup>

74. Makena’s patient education brochure extols Makena’s effectiveness: “HELP GIVE YOUR BABY MORE TIME TO DEVELOP,” “Makena...helps give bab[ies] more time to develop,” and “Every week counts when you’re pregnant.”<sup>48</sup>

75. AMAG’s conduct was and is unlawful in that its conduct, for example, violated the prohibition on making false or misleading statements in connection with the sale of prescription drugs found in 21 C.F.R. 202.1(e)(6-7) and 21 U.S.C. §§ 321(n), 352(a).

76. But for such misleading and deceptive statements and but for AMAG’s material omissions – which AMAG intended Plaintiffs and class members would rely on – Plaintiffs and Class members would not have purchased and been injected with Makena.

77. AMAG’s misrepresentations and material omissions were likely to (and in fact did) mislead expecting mothers concerned about preterm birth, i.e., the Plaintiffs and class members, who acted reasonably under the circumstances. Had AMAG adequately disclosed that Makena is not effective to Plaintiffs and class members,

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<sup>47</sup> *Id.*

<sup>48</sup> Makena Patient Education Brochure (English), Makena (hydroxyprogesterone caproate injection), [https://makena.com/wp-content/themes/MakenaDTP/file/Makena\\_Auto-Injector\\_Patient\\_Education\\_Brochure\\_-\\_English.pdf](https://makena.com/wp-content/themes/MakenaDTP/file/Makena_Auto-Injector_Patient_Education_Brochure_-_English.pdf).

Plaintiffs and class members would not have purchased Makena, and would not have undergone weekly injections of Makena, often with significant and painful side effects such as bruising, skin irritation, painful rashes, and nausea. Such misrepresentations and omissions by AMAG were material and were at minimum a substantial factor in influencing Plaintiffs and the class members' decision to purchase and be injected with Makena. Accordingly, Plaintiffs and class members reasonably relied (at minimum) on AMAG's deceptive failure to disclose Makena's ineffectiveness, and would not have purchased and been injected with Makena but for AMAG's material omissions and misrepresentations.

#### **CLASS ACTION ALLEGATIONS**

78. Plaintiffs bring these consolidated class actions under Fed. R. Civ. P. 23 on behalf of the following state-wide classes:

##### ***The New Jersey Class***

All purchasers of Makena for personal, family, or household purposes in New Jersey from January 3, 2014 to the present.

##### ***The California Class***

All purchasers of Makena for personal, family, or household purposes in California from January 13, 2016 to the present.

##### ***The Kansas Class***

All purchasers of Makena for personal, family, or household purposes in Kansas from November 4, 2016 to the present.

##### ***The Missouri Class***

All purchasers of Makena for personal, family, or household purposes in Missouri from November 1, 2014 to the present.

***The New York Class***

All purchasers of Makena for personal, family, or household purposes in New York from November 12, 2016 to the present.

***The Wisconsin Class***

All purchasers of Makena for personal, family, or household purposes in Wisconsin from February 4, 2017 to the present.

Excluded from each Class are AMAG's employees and members of their immediate families; any federal, state, or local governmental entities; any judicial officers presiding over this action and members of their immediate family and judicial staff; and any person who timely opts out of any class consistent with the Court's order certifying a class.

79. Members of each Class are so numerous that their individual joinder herein is impracticable. On information and belief, each Class numbers at least in the hundreds, if not thousands. The precise size of each Class and the identities of their members are unknown to Plaintiffs at this time but will be determined through discovery. Class members may be notified of the pendency of this action by publication and/or mailing through AMAG's sales records.

80. For each Class, common questions of law and fact exist as to all Class members and predominate over questions affecting only individual Class members.

Common legal and factual questions include, but are not limited to:

- a. whether AMAG advertised or marketed Makena in a way that was false or misleading;
- b. whether Makena failed to conform to the representations, which were

published, disseminated, and advertised by AMAG to Plaintiffs and the Class;

c. whether AMAG concealed from Plaintiffs and the Class that Makena did not conform to its stated representations;

d. whether AMAG has engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sales of Makena; and

e. whether AMAG was unjustly enriched by its conduct;

81. Plaintiffs' claims are typical of the claims of the Class members as all Class members are similarly affected by AMAG's wrongful conduct. Plaintiffs have no interests antagonistic to the interests of other Class members as Plaintiffs and all Class members have sustained economic injury arising out of AMAG's violations of law as alleged herein.

82. Plaintiffs are adequate representatives of their respective Classes because their interests do not conflict with the interests of the Class members they seek to represent. Plaintiffs have retained counsel competent and experienced in prosecuting class actions. The interests of Class members will be fairly and adequately protected by Plaintiffs and their counsel.

83. The class mechanism is superior to other available means for the fair and efficient adjudication of the claims of Plaintiffs and Class members. Each Class member may lack the resources to undergo the burden and expense of individual prosecution of the complex and extensive litigation necessary to establish AMAG's liability. Mass individualized litigation increases the delay and expense to all parties and multiplies the burden on the judicial system presented by the complex legal and



factual issues of this case. Mass individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of AMAG's liability. Class treatment of the liability issues will ensure that all claims can be consistently and efficiently adjudicated.

**COUNT I: VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT  
(NEW JERSEY CLASS)**

84. Plaintiffs Zamfirova and Maher re-allege the allegations set forth in paragraphs 18 – 77 as if fully set forth herein.

85. Plaintiffs Zamfirova and Maher bring this claim on behalf of themselves and the New Jersey Class under the New Jersey Consumer Fraud Act, codified at N.J.S.A. 56:8-2.

86. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

87. AMAG's statements that Makena was effective in reducing preterm births constitute unconscionable commercial conduct, deception, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of a material fact with intent of reliance in connection with consumer sales of Makena in violation of the New Jersey Consumer Fraud Act.

88. These falsities include but are not limited to AMAG's statements:

- a. “Makena helps you get closer to term.”
- b. “Makena ... is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who’ve unexpectedly delivered one baby too early (before 37 weeks) in the past.”
- c. “Makena gives moms an extra layer of support.”
- d. “receiving the weekly injections of Makena is giving me the peace of mind knowing that I’m doing everything I can to help prolong this pregnancy.”
- e. “looking back, Makena gave me hope that I had a better chance of delivering Olivia full term.”
- f. “Makena ... helps give bab[ies] more time to develop.”

Each of these statements was false and deceptive.

89. Plaintiffs and all New Jersey Class members suffered an ascertainable loss caused by AMAG’s misrepresentations because Plaintiff and New Jersey Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

90. Plaintiffs and all New Jersey Class members suffered an ascertainable loss caused by AMAG’s misrepresentations because Plaintiff and New Jersey Class members were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections.

**COUNT II: VIOLATION OF THE CALIFORNIA BUS. & PROF. CODE § 17200  
(CALIFORNIA CLASS)**

91. Plaintiffs Amaro, Gomez, Nelson, and Torres re-allege the allegations in

paragraphs 18 – 77 as if fully set forth herein.

92. Plaintiffs bring this claim on behalf of themselves and the California Class under the California Bus. & Prof. Code § 17200 *et seq.* for restitution as a result of AMAG’s unlawful, unfair, or fraudulent practices.

93. AMAG misrepresented Makena’s effectiveness at preventing preterm births in connection with the sale and advertisement of Makena.

94. AMAG’s statements that Makena was effective in reducing preterm births constitute unlawful, unfair or fraudulent business acts or practices and unfair, deceptive, untrue or misleading advertising in violation of the California Unfair Competition Law.

95. These falsities include but are not limited to AMAG’s statements that:

- a. “Makena helps you get closer to term.”
- b. “Makena ... is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who’ve unexpectedly delivered one baby too early (before 37 weeks) in the past.”
- c. “Makena gives moms an extra layer of support.”
- d. “receiving the weekly injections of Makena is giving me the peace of mind knowing that I’m doing everything I can to help prolong this pregnancy.”
- e. “looking back, Makena gave me hope that I had a better chance of delivering Olivia full term.”
- f. “Makena ... helps give bab[ies] more time to develop.”

96. AMAG's conduct violated each prong of the UCL: i) it was unlawful in that it, for example, violated the prohibition on making false statements in connection with the sale of prescription drugs found in 21 C.F.R. 202.1(e)(6-7) and 21 U.S.C. §§ 321(n), 352(a); it was unfair in causing Class members to make decisions based on false information; and iii) it was fraudulent in that AMAG knew or should have known its marketing statements were not true.

97. Plaintiffs and all California Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiffs and California Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

98. Additionally, Plaintiffs and the California Class were injured by virtue of having to undergo and purchase weekly injections of a drug that did not work, including all the wasted time associated with taking such injections.

99. As a result of AMAG's unlawful, unfair, or fraudulent business practices, AMAG has reaped unfair benefits and illegal revenues and profits at the expense of Plaintiffs and the California Class. As a result, AMAG should be required to disgorge its ill-gotten gains and restore such monies to Plaintiffs and the California Class.

100. Under California Business and Professions Code § 17203, Plaintiffs and class members seek such orders or judgments as may be necessary to prevent

AMAG's future use of its unlawful, unfair or fraudulent practices, and to restore to Plaintiffs and the California Class any money or property that may have been acquired by means of AMAG's unfair competition

101. AMAG's unlawful, unfair or fraudulent business practices entitle Plaintiffs to seek preliminary and permanent injunctive relief, including but not limited to an order requiring AMAG to account for, disgorge and restore to Plaintiffs and the California Class its unlawfully obtained gains.

**COUNT III: CALIFORNIA CONSUMER'S LEGAL REMEDIES ACT  
(CALIFORNIA CLASS)**

102. Plaintiffs Amaro, Gomez, Nelson, and Torres re-allege the allegations set forth in paragraphs 18 – 77 as if fully set forth herein.

103. Plaintiffs Amaro, Gomez, Nelson, and Torres bring this claim on behalf of themselves and the California Class under the California Consumer Legal Remedies Act (CLRA), Cal. Civ. Code § 1770 *et seq.*

104. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

105. AMAG's statements that Makena was effective in reducing preterm births constitute unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising in violation of the CLRA.

106. These falsities include but are not limited to AMAG's statements that:

- a. "Makena helps you get closer to term."

- b. “Makena ... is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who’ve unexpectedly delivered one baby too early (before 37 weeks) in the past.”
- c. “Makena gives moms an extra layer of support.”
- d. “receiving the weekly injections of Makena is giving me the peace of mind knowing that I’m doing everything I can to help prolong this pregnancy.”
- e. “looking back, Makena gave me hope that I had a better chance of delivering Olivia full term.”
- f. “Makena ... helps give bab[ies] more time to develop.”

Each of these statements was false and deceptive and constituted acts or practices prohibited under the CLRA.

107. Plaintiffs and all California Class members suffered an ascertainable loss caused by AMAG’s misrepresentations because Plaintiffs and the California Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

108. Additionally, Plaintiffs and the California Class suffered ascertainable losses of money and property caused by AMAG’s misrepresentations by virtue of having to undergo weekly injections of a drug that did not work, including all the wasted time and pain associated with taking such injections.

109. As a result of AMAG’s unfair business practices, AMAG has reaped unfair benefits and illegal profits at the expense of Plaintiffs and the California Class.

AMAG should thus be made to disgorge its ill-gotten gains and restore such monies to Plaintiffs and the California Class.

110. Under Cal. Civ. Code § 1780, Plaintiffs and the California Class seek such orders or judgments as may be necessary to prevent AMAG's future use of its unfair and unlawful practices, for their actual damages, for an order enjoining the unlawful conduct identified herein, for restitution, attorney fees and costs, and for any other relief the court deems proper.

111. AMAG's unfair business practices entitle Plaintiffs an order requiring AMAG to account for, disgorge and restore to Plaintiffs and the California Class its unlawfully obtained gains.

**COUNT IV: VIOLATION OF THE KANSAS CONSUMER PROTECTION ACT  
(KANSAS CLASS)**

112. Plaintiff Gill re-alleges the allegations set forth in paragraphs 18 – 77 as if fully set forth herein.

113. Plaintiff Gill brings this claim on behalf of herself and the Kansas Class under the Kansas Consumer Protection Act, codified at Kan. Stat. Ann. § 50-623 et seq.

114. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

115. AMAG's statements that Makena was effective in reducing preterm births constitute deceptive acts and practices in violation of Kansas Consumer Protection

Act.

116. These falsities include but are not limited to AMAG's statements that:

- a. "Makena helps you get closer to term."
- b. "Makena ... is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."
- c. "Makena gives moms an extra layer of support."
- d. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."
- e. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."
- f. "Makena ... helps give bab[ies] more time to develop."

Each of these statements was false and deceptive and constituted an unconscionable act or practice specifically proscribed under Kan. Stat. Ann. §§ 50-626 and 50-627.

117. Plaintiff Gill and all Kansas Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiff Gill and Kansas Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

118. Plaintiff Gill and all Kansas Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiff Gill and Kansas Class members were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections.



**COUNT V: VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT  
(MISSOURI CLASS)**

119. Plaintiff Barnes re-alleges the allegations set forth in paragraphs 18-77 as if fully set forth herein.

120. Plaintiff Barnes brings this claim on behalf of herself and the Missouri Class under the Missouri Merchandising Practices Act, RSMo §§ 407.010 et seq.

121. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

122. AMAG's statements that Makena was effective in reducing preterm births constitute "deception, fraud ... false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact," in violation of the Missouri Merchandising Practices Act.

123. These falsities include but are not limited to AMAG's statements:

- g. "Makena helps you get closer to term."
- h. "Makena ... is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."
- i. "Makena gives moms an extra layer of support."
- j. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."
- k. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."

1. “Makena ... helps give bab[ies] more time to develop.”

Each of these statements was false and deceptive.

124. Plaintiff Barnes and all Missouri Class members suffered an ascertainable loss caused by AMAG’s misrepresentations because Plaintiff Barnes and Missouri Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

125. Plaintiff Barnes and all Missouri Class members suffered an ascertainable loss caused by AMAG’s misrepresentations because Plaintiff Barnes and California Class members were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections.

**COUNT VI: VIOLATION OF NEW YORK GEN BUS. LAW SECTION 349(A)  
(NEW YORK CLASS)**

126. Plaintiffs Faughnan and Maltese re-allege the allegations set forth in paragraphs 18 – 77 as if fully set forth herein.

127. Plaintiffs Faughnan and Maltese bring this claim on behalf of themselves and the New York Class under New York’s General Business Law (GBL) §349(a).

128. AMAG’s conduct as alleged herein violates § 349(a) of the GBL, which prohibits deceptive acts or practices.

129. AMAG’s acts and practices were consumer-oriented, as they affected not only Plaintiffs but similarly situated consumers as well, and they had the potential to affect even more consumers.

130. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

131. AMAG's statements that Makena was effective in reducing preterm births constitute unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising in violation of the GBL.

132. These falsities include but are not limited to AMAG's statements that:

- a. "Makena helps you get closer to term."
- b. "Makena ... is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."
- c. "Makena gives moms an extra layer of support."
- d. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."
- e. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."
- f. "Makena ... helps give bab[ies] more time to develop."

Each of these statements was false and deceptive and constituted acts or practices prohibited by the GBL.

133. Plaintiffs and all New York Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Makena had a premium price when the product was worth zero or close to zero based on its actual attributes.

134. Additionally, Plaintiffs and the New York Class suffered ascertainable

losses by virtue of having to undergo weekly injections of a drug that did not work, including all the wasted time associated with taking such injections.

135. Plaintiffs and all New York Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiffs Faughnan and Maltese and New York Class members were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections.

136. Pursuant to GBL § 349(h), Plaintiffs Faughnan and Maltese and the New York Class seek an award of damages and/or statutory penalties, whichever is greater, injunctive relief, treble damages, and attorneys' fees.

**COUNT VII: VIOLATION OF THE WISCONSIN DECEPTIVE TRADE PRACTICES ACT  
(WISCONSIN CLASS)**

137. Plaintiffs Brady and Meffert re-allege the allegations set forth in paragraphs 18-77 as if fully set forth herein.

138. Plaintiffs Brady and Meffert bring this claim on behalf of themselves and the Wisconsin Class under the Wisconsin Deceptive Trade Practices Act (WDTPA).

139. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

140. AMAG's statements that Makena was effective in reducing preterm births constitute deceptive acts and practices in violation of the WDTPA.

141. These falsities include but are not limited to AMAG's statements that:

m. "Makena helps you get closer to term."

- n. “Makena ... is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who’ve unexpectedly delivered one baby too early (before 37 weeks) in the past.”
- o. “Makena gives moms an extra layer of support.”
- p. “receiving the weekly injections of Makena is giving me the peace of mind knowing that I’m doing everything I can to help prolong this pregnancy.”
- q. “looking back, Makena gave me hope that I had a better chance of delivering Olivia full term.”
- r. “Makena ... helps give bab[ies] more time to develop.”

Each of these statements was a false and deceptive act or practice under the WDTPA.

142. Plaintiffs Brady and Meffert and all Wisconsin Class members suffered an ascertainable loss caused by AMAG’s misrepresentations because Plaintiffs Brady and Meffert and Wisconsin Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

143. Plaintiffs Brady and Meffert and all Wisconsin Class members suffered an ascertainable loss caused by AMAG’s misrepresentations because Plaintiffs Brady and Meffert and Wisconsin Class members were repeatedly and painfully injected with a worthless drug, including all the lost time associated with the injections.

#### **COUNT VIII: UNJUST ENRICHMENT (ALL CLASSES)**

144. Plaintiffs re-allege the allegations set forth in paragraphs 18-77 as if fully set forth herein.

145. Plaintiffs and all Class members conferred a benefit on AMAG by

purchasing Makena.

146. AMAG knowingly benefited at Plaintiffs' and the Class members' expense by the sale of Makena by collecting the price thereof, which consumers paid because of AMAG's false and misleading advertising and representations and/or omissions.

147. AMAG's retention of the revenues from Plaintiffs and Class members' purchases of Makena, under these circumstances, is unjust and inequitable because consumers were misled by AMAG to believe that they were receiving a product effective at preventing preterm births when it was not.

148. Plaintiffs and Class members were injured because they purchased a product, they otherwise would not have purchased, due to AMAG's falsities, misrepresentations, and/or omissions.

149. Because AMAG's retention of the non-gratuitous benefit conferred on it by Plaintiffs and the Class members is unjust and inequitable, AMAG must pay restitution to Plaintiff and the Class members, as ordered by the Court.

#### **PRAYER FOR RELIEF**

Plaintiffs, on behalf of themselves and their respective Classes, request relief as follows:

A. That the Court determine that each of the claims alleged herein may be maintained as a class action under Federal Rule of Civil Procedure 23, that Plaintiffs be named as Class Representatives of each of their respective Classes, that the

undersigned be named as Class Counsel, and that the Court direct that notice of this action be given to Class members;

B. That the Court enter an order declaring that AMAG's actions, as set forth in this Complaint, violate the state laws set forth above;

C. That the Court award Plaintiffs and their respective Classes all compensatory and statutory damages, punitive damages, and/or restitution in an amount to be determined at trial;

D. That the Court issue appropriate injunctive and other equitable relief;

E. That the Court award Plaintiffs and their respective Classes pre- and post-judgment interest;

F. That the Court award Plaintiffs their costs of suit, including reasonable attorneys' fees and expenses, including costs of consulting and testifying experts; and

G. That the Court award any and all such other relief as the Court may deem just and equitable.

### **JURY DEMAND**

Plaintiffs hereby demand a trial by jury on all claims so triable.

Dated: April 2, 2020

Respectfully submitted,

**PAUL LLP**

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**ATTORNEYS FOR PLAINTIFFS AND THE PROPOSED CLASSES**



**CERTIFICATE OF SERVICE**

I certify that on April 2, 2020, I electronically filed the above document with the Court's electronic filing system, which will send notification to all counsel of record.

/s/Bruce D. Greenberg  
Bruce D. Greenberg